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April 4, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, room 1061
Rockville, Maryland 20852

Re: Docket No. 02N-0278 (Prior Notice)

Dear Sir or Madam:

The American Frozen Food Institute ("AFFI") welcomes this opportunity to provide comments to the U.S. Food and Drug Administration ("FDA") with regard to the proposed rule to implement Section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("the Act"). AFFI is the national trade association representing frozen food manufacturers, their marketers and suppliers. AFFI's 511 member companies are responsible for approximately 90 percent of the frozen food processed annually in the United States, valued at more than $60 billion. AFFI members are located throughout the country and are engaged in the manufacture, processing, transportation, distribution, and sale of products nationally and internationally.

Among other requirements, Section 307 of the Act requires that FDA issue regulations requiring the submission of notice in advance of any importation of food into the U.S. AFFI recognizes that the agency's task in implementing this provision is a complex one. It must balance the need to improve the quantity and quality of imported food inspections with the importance of minimizing disruptions to trade and the overall food supply. AFFI appreciates the agency's apparent willingness to work closely with industry in developing final regulations that reach the appropriate balance. AFFI is concerned, however, that certain aspects of the proposal would unduly burden trade, while doing little to advance the stated goal of the Act, namely to prevent and respond to potential and actual threats of bioterrorism by enabling FDA inspections of imported food at ports of entry.

To address these concerns, AFFI recommends FDA reduce the amount of information it would require in a prior notice submission to more closely mirror the information required by the Act. In so doing, AFFI believes the agency may be able to utilize existing FDA/U.S. Customs Service ("Customs") information collection systems, which would minimize commercial disruptions and save agency time and resources. For the same reasons, AFFI encourages the agency to reduce the minimum required notice period and to provide greater flexibility for amendments and updates. We also urge FDA to retain its proposed definition of originating country and confirm that grower information need not be submitted for multi-ingredient processed foods, in response to the agency's specific requests for comments on these issues. Our comments are outlined in detail below and reiterate, in part, the comments AFFI submitted to the Office of Management and Budget ("OMB"), attached for your convenience.

I. Threshold Issue – Implementation of Final Rule

In addition to AFFI's comments on the substantive aspects of the proposal, AFFI would like to take this opportunity to address an issue of vital importance—implementation of the final rule. AFFI acknowledges that the Bioterrorism Act imposes a deadline by which the prior notice system must be up and running. The Institute fears, however, that commerce at America's borders may be paralyzed if the agency starts placing articles of food on hold for minor technical issues as both industry and FDA grow accustomed to the new system. The Institute suggests, therefore, that it would be appropriate for the agency to exercise its enforcement discretion during the first six months to one year after the effective date of the final rule in situations where there are only minor technical problems associated with a prior notice submission, especially where it is documented that the product or ingredient has been imported routinely between the shipper and receiver, without incident, over an extended period of time.

II. Addressing Practical Challenges – Use of Existing Systems

FDA proposes to require far more information in prior notice submissions than is required by the Bioterrorism Act. If, however, the proposal were revised to mirror more closely the statute's limited requirements, AFFI believes that FDA would be able to utilize the existing information collection systems (i.e., the ABI/OASIS interface) to collect prior notice information, rather than spending limited resources on creating an entirely new prior notice system. More importantly, AFFI believes that utilization of the existing Automated Broker Interface/Operational and Administrative System for Import Support (ABI/OASIS) interface, rather than an independent prior notice system, would better enable the agency to inspect potentially adulterated foods at ports of entry. AFFI, therefore, requests FDA to reduce the amount of information that would be required in a prior notice submission to that information specifically required by the Bioterrorism Act. In turn, AFFI urges the agency to modify the existing ABI/OASIS interface for the purposes of collecting and processing the limited prior notice information. _/

As an important threshold issue, AFFI notes that FDA intends to allow prior notice to be submitted through Customs' Automated Commercial Environment ("ACE") once it is fully operational. Thus, the agency's proposed prior notice system is an interim provision that will be obsolete once ACE is fully operational, expected in 2005. It is, therefore, not readily apparent to AFFI why the agency would use its limited resources to develop an entirely new system if limiting the information required in prior notice to that required by the Act would allow the submission of prior notice through existing information collection systems at a much lower cost to the government.

_/ AFFI recognizes that FDA and Customs determined that the ABI/OASIS interface could not be altered to accommodate the data requirements of the proposed prior notice regulation by the December 12, 2003 deadline. It does not appear, however, that the agencies considered whether the interface could be modified to accommodate less information than would be required by the proposal.

Specifically, the Bioterrorism Act requires importers to submit in advance of the importation of an article of food the identity of the following: the article of food; the manufacturer and shipper; the grower, if known; the originating country; the shipping country; and the anticipated port of entry. AFFI understands that certain additional information such as arrival time and FDA registration numbers would be helpful, though not necessary, to fulfill the stated purpose of the prior notice requirement (i.e., to enable the article to be inspected at the port of entry, if necessary). FDA proposes, however, to require much more information than AFFI believes necessary to fulfill this goal, as explained further below in Section III of our comments. AFFI believes that elimination of this additional information would enable the agency to utilize the existing ABI/OASIS interface for prior notice submissions, such that the agency could use the information submitted in the prior notice to determine whether to inspect an article of food under Section 801(a) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), as Congress intended. _/

Importers already submit much of the same information required by the Act and proposal into FDA's OASIS system through the Customs Automated Broker Interface ("ABI"), a part of Customs' larger Automated Commercial System ("ACS"). AFFI understands that this information includes: the originating country; the shipping country; product identity information, including FDA product code and quantity; a commercial description of the product; manufacturer identity, including the facility's address if it is a low-acid canned food or other facility subject to FDA license/registration/listing requirements; and shipper information. The OASIS system also allows submission of the FDA registration number of food canning facilities. In addition, we understand that the system allows for the submission of information identifying the consignee of the product.

_/ The conferees to the legislation "intend[ed] for the Secretary to expeditiously promulgate the required regulations *so* that efficiency of food import inspections may be improved." 148 CONG. REC. H2858 (daily ed. May 22, 2002) (statement of Rep. Shimkus (R-Ill.)).

Based on the information provided, FDA makes a determination as to the admissibility of the product under Section 801(a) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"). If FDA were to modify the OASIS system and ABI interface to take into account the extra information required by the Act (i.e., port of entry and grower information), along with the anticipated arrival time and relevant FDA registration numbers, the agency would have the ability to determine, at roughly the same time, whether to hold an article for purposes of prior notice and/or inspect it pursuant to Section 801(a) of the FFDCA, as Congress intended.

AFFI appreciates that implementing the prior notice requirement through existing FDA/Customs information systems will present practical difficulties. As outlined above and further below, however, the bulk of the necessary infrastructure is already in place, if the agency places reasonable limitations on the information it would require to be submitted. AFFI understands that Customs' ACS already permits brokers to enter OASIS data via the ABI prior to actual importation of a shipment, although data is not currently transmitted to FDA until entry is actually made.

AFFI suggests FDA and Customs modify the ABI/OASIS interface in two critical ways to allow submission of prior notice information: (1) all OASIS data submitted by brokers in the ABI system prior to importation should be immediately transmitted to FDA; and (2) a broker that enters OASIS data prior to importation should receive an immediate acknowledgement of the entry. If possible, the ABI system should assign a unique number to the record created by the broker at the time OASIS data is entered that will remain constant and constitute the entry number for the shipment when importation is finally made. To perfect this system, the OASIS data screen in the ABI should be modified to allow, to the extent necessary, entry of: the limited additional information required by the Act; the anticipated arrival time; and relevant FDA registration numbers. _/

_/ If systems constraints still prevent such data transfer, AFFI urges FDA to build a link between the new prior notice system and the ABI/OASIS interface such that relevant information in a prior notice submission would be forwarded automatically to the ABI/OASIS interface. This would at least avoid the imposition of duplicative data entry on import brokers.

Utilizing existing information collection systems would save the agency much of the $4.4 billion earmarked for the creation of an entirely new prior notice system and maintain the connection to Customs that is necessary to ensure the smooth coordination of efforts related to imported foods. It would also save importers from having to enter much of the same information into two separate databases (i.e., the OASIS data entry screen and the prior notice system). In all, adjusting the information required to be submitted to OASIS would enable industry and FDA to comply with Congressional directives without wasting resources that could be better used to help build a "smarter," risk-based system for the selection of food shipments for inspection.

In that regard, to reiterate another point made in our initial comments to FDA, AFFI urges the agency to take this opportunity to modify OASIS to allow for submission and consideration of other information that will assist the agency in making better, more risk-based sampling selections. FDA might, for example, utilize Customs' "low risk" importer category. A broker giving prior notice of a shipment by an importer in this category could enter the importer's unique "low risk" importer identification number in the OASIS data screen. Similar modifications to the OASIS screen could be made to ensure that a broker and/or importer participating in the Customs-Trade Partnership Against Terrorism (CTPAT) program are identified as such to FDA.

III. Requests for Specific Deletions in the Prior Notice Form

At a minimum, AFFI requests FDA to delete the proposed requirements to provide: the lot or code numbers or other identifiers; Customs date and port of entry; and contact information for the submitter, manufacturer, shipper, importer, owner, and consignee of the article of food, if a registration number is provided.

A. Lot or Code Numbers

FDA proposes to require submission of the "lot, code or other identifying number." The agency states in the preamble that these numbers would represent the identification number or code of a production lot, which is needed to more specifically identify a product. It is unclear, however, how this information would be necessary to further enable inspections at ports of entry, which is the stated purpose of the prior notice requirement. The prior notice submission would already include the complete FDA product code, common or usual name of the product, and manufacturer identification. To also require production lot information could not possibly add value to the agency's determination of whether to inspect a specific product at the port of entry and, therefore, should not be required. Moreover, the terms "lot, code or other identifying number" are so vague as to be unenforceable.

B. Customs Date and Port of Entry

Along those same lines, AFFI encourages the agency to delete the requirement to provide information as to the Customs date and port of entry. As noted by FDA, the Customs date of entry may be days after the date of entry provided for prior notice purposes, just as the Customs port of entry may be different than FDA's port of entry. It is difficult to discern, therefore, how this information would be useful to the agency in determining whether to inspect the product offered for import at the port where the food first arrives in the U.S.

C. Contact Information for Registered Facilities

Finally, AFFI notes that the proposal would require the submission of the address, e-mail address, and telephone, facsimile, and registration numbers for the manufacturer, shipper, importer, owner, and consignee. Because FDA will have access to this contact information in its registration database, AFFI encourages the agency to require only the FDA registration number of the aforementioned entities. This would significantly decrease the burden of prior notice submissions, without decreasing the amount of information available to the agency.

IV. Minimum-Required Period of Notice

AFFI strongly urges the agency to adopt shorter, rolling minimum prior notice deadlines, rather than the proposed fixed time of noon the calendar day before arrival. _/ A shorter prior notice period that is not fixed to a certain time of day, but rather tied to the arrival of an individual shipment of food at the port of entry, would avoid the inevitable bombardment of prior notice submissions FDA would receive at noon every day under the proposal. AFFI strongly believes that the agency should establish no more than a four-hour minimum period for Canadian and Mexican border crossing ports of entry and an eight-hour minimum for all other ports.

AFFI notes that in our initial comments to FDA, the Institute urged the agency to adopt a minimum-required notice period of two hours for border crossing ports of entry. However, AFFI believes that a minimum of four hours may be adequate if the agency would allow increased flexibility to amendments to product identity information and updates to anticipated arrival time, as suggested below. The fact remains that many food facilities that routinely ship products to the U.S. from Canada and Mexico are located very close to the border. Based on information provided by our members, it appears that importers of products from these facilities would not always know exact quantities or the exact time of arrival at the border when submitting prior notice, even with the shorter notice period.

_/ The proposal's deadline for prior notice submission would essentially require 36 hour advanced notice for entries submitted after noon on the calendar day before the article's scheduled arrival, but only 12 hours for those submitted before noon. It is likely, therefore, that most brokers would aim to submit prior notice shortly before noon.

Additionally, AFFI is concerned that the proposed minimum required notice period would act as an effective trade barrier to products from Canada or Mexico. For instance, one large food processor with facilities located close to the Canadian border advised AFFI that, for various reasons, customers order "emergency" shipments of products that are often received, loaded, and shipped across the U.S./Canadian border within a single day. The proposed minimum notice period would not allow this practice of filling "emergency orders" to continue, severely straining customer relations and imposing an effective barrier to trade on products imported through border crossing ports of entry.

AFFI recognizes that longer minimum notice periods may be appropriate for other types of ports of entry, such as those receiving ocean freight. AFFI believes that an eight-hour advance notice period would be viable from the point of view of brokers and importers and give FDA a substantial period of time to determine whether sampling/inspection of any particular shipment is warranted.

Imposing a rolling four- or eight-hour advance notice period, instead of tying the notice requirement to a fixed time of day, would lead to more certainty in the initial prior notice submission, thereby reducing the number of amendments, updates, and cancellations that must be processed by FDA. It would remain appropriate, of course, to allow for amendments to product identity and arrival time, as the flexibility afforded by such adjustments is vital to ensuring the smooth flow of commerce into the U.S. Despite shorter prior notice periods, unanticipated traffic, vehicle breakdowns, and other factors may substantially delay arrival time, creating the need for updates. In addition, amendments to product identity are needed, especially with respect to border crossing ports, in the event that the quantity or exact type of product (e.g., romaine lettuce versus green leaf lettuce) is not known at the time notice is submitted.

In fact, the adjustments to product identity that would be allowed in amendments are so minor that they would not likely alter the agency's admissibility determination. AFFI, therefore, encourages the agency to allow such changes upon the entry of an article of food at the port of entry, rather than requiring them at least two hours prior to arrival. Eliminating the two-hour deadline would provide ultimate flexibility, without compromising food security.

For the same reason, AFFI suggests revising the requirements applicable to updates to expand the window of time during which carriers could arrive at the border of entry without having to submit an update as to arrival time. FDA proposes to require updates to the arrival time and port of entry if the carrier will be more than one hour earlier or three hours later than anticipated. As stated above, however, factors such as traffic, weather, and loading delays may prevent trucks from reaching border crossing ports of entry within a four window, necessitating submission of updates on a regular basis. To avoid the strain on agency resources that processing this information would impose, AFFI suggests the agency require importers to notify FDA at least one hour before the carrier reaches the border if the truck might arrive more than one hour earlier than anticipated. In addition, FDA could require updates if the carrier might arrive more than eight hours late.

V. Authorized Submitter of Prior Notice

AFFI strongly urges FDA to allow foreign companies that do not reside or maintain a place of business in the United States to submit prior notice of food imports. The proposed rule would allow a purchaser or importer of an article of food who resides or maintains a place of business in the United States to submit prior notice, in addition to an agent who resides or maintains a place of business in the United States acting on the behalf of the U.S. purchaser or U.S. importer, such as an import broker. FDA states in the preamble that it chose these U.S. entities because, among other reasons:

> [the agency believes] that it is the U.S. importer or U.S. purchaser who orders or buys the article of food, thereby initiating its importation into the United States. These persons thus should possess, or have the ability to obtain, the information required to be submitted in the prior notice within the time period in proposed Sec. 1.286.

In many instances, however, the foreign shipper or manufacturer would be the most appropriate entity to submit prior notice. Allowing entities that do not reside or maintain a place of business in the U.S. to submit prior notice would greatly simplify processing for both industry and FDA. Many carriers, including trucks, transport orders for several different customers. If individual customers, as the purchasers of the product, were to submit independent prior notices for only their portion of a truckload destined for multiple customers, FDA would have to deal with five prior notice submissions, not one. Further, one customer's mistake in a prior notice submission could result in the entire truckload being delayed or held by FDA, and the shipper or manufacturer would have to alert every single customer that submitted prior notice for a particular truckload if there were a need to update arrival information.

VI. Definition of Originating Country

The proposal would require prior notice submissions to include the country from which the article of food was shipped, further defining the shipping country as "the country in which the article of food was loaded onto the conveyance that brings it to the United States." In the preamble to the proposal, FDA requests comment on whether this term should include the countries of intermediate destination. AFFI strongly urges FDA to retain the current definition, as the additional information would not advance the goal of the prior notice submission.

VII. Clarification Regarding Grower Information

The Bioterrorism Act requires prior notice submissions to include grower information, if known. In the preamble to the proposal, FDA requests comments on whether the Act gives FDA the flexibility to exempt from this requirement "processed foods" produced with products from more than one grower. AFFI believes this statement implies that the proposal would require information on the growers of individual ingredients of multi-ingredient processed foods, if known.

It would not be financially feasible for processors to separate production lots based on the identity of the individual grower(s) of the fruits, vegetables or ingredients derived therefrom. Moreover, FDA staff has indicated in recent public meetings that the grower identification requirement is not intended to apply to multi-ingredient foods. AFFI, therefore, strongly urges FDA to clarify this point in the final rule, since it does not seem apparent from the plain language of the proposal.

VIII. Quantity Information

Finally, AFFI urges FDA either to accept approximate quantity information or to treat changes to quantity information as updates, rather than amendments. It is our understanding that the proposal would require importers to note on the prior notice submission when amendments to product identity, including quantity, will be forthcoming. For many orders, however, the exact quantities in a shipment will not be known until shortly before the truck or vessel is to be loaded, which may be long after the initial prior notice has been submitted to the agency. This is especially true with respect to border crossing ports of entry.

This often occurs because plants estimate production based on maximum capacity. Their initial estimate for importation, therefore, may be high. That estimate is refined downward over time as production time is anticipated and accounted for and final numbers for purposes of tariff calculations are prepared.

Since, in many circumstances, import brokers would be able to provide a likely quantity, but would not be able to verify, or know for sure, that the estimated quantity will be correct until after the prior notice deadline, importers would often have to indicate on prior notices that an amendment with respect to quantity will follow in order to avoid having to cancel and resubmit the notice.

To avoid the need to submit and process unnecessary amendments in the event that the estimated quantity turns out to be the actual quantity, AFFI suggests allowing approximate quantity information, which should certainly be accurate enough for FDA's admissibility decision. In the alternative, AFFI recommends treating changes to quantity as it would updates to arrival information, rather than amendments to product identity, such that import brokers would not have to note in the initial prior notice that the actual quantity may differ than the anticipated quantity.

IX. Holding Facilities

For product that would need to be diverted to a secure warehouse under the proposal, FDA should provide a short list of such facilities where FDA inspectors can be available and the list must include adequate cold/freezer storage. If product is not diverted but rather held at the port of entry, the agency should clarify its plans to ensure the integrity of perishable products.

X. Samples

AFFI's members advise the Institute that facilities receive thousands of samples each year from suppliers with no advanced notice of their pending arrival. AFFI believes that these routine, but unscheduled deliveries could be allowed to continue without undermining the goal of protecting the security of imported food. It is AFFI's understanding that this would be feasible as long as the sample shipments in question:

(a) are addressed to and received by only the permanently established analytical facilities or responsible individuals of the receiving companies;

(b) are used solely for analytical and related purposes or are disposed of in a manner that precludes them from being used in making products for public consumption; and

(c) are generally small in weight or volume.

Thus, AFFI proposes that FDA exempt samples clearly marked as "samples – not for consumer consumption," that are accompanied with a certifying statement describing the intended use. Limiting the eligible recipients, disposition, and size of sample shipments as well as certifying their intended use would avoid burdening commerce without resulting in any threat to food security.

XI. Conclusion

AFFI appreciates the opportunity to comment with regard to the agency's proposed implementation of the Act's prior notice provisions. AFFI looks forward to working with FDA to develop other required rulemakings in a manner that will maximize public health protection without unduly burdening importers or interfering with the smooth functioning of the commercial food supply. Please do not hesitate to contact us if you have any questions.

Respectfully Submitted,

Leslie G. Sarasin

Leslie G. Sarasin, CAE
President and
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